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REMARKS

Claims 76-77, 97-98, 107-108, 134-135, 142-145, 158, 161, 178-180, 183 and 184 were pending in the subject application. By this Amendment, applicants have canceled claims 178-180 without prejudice; amended claims 183-184; and added new claims 185-191. Accordingly, upon entry of this Amendment, claims 76-77, 97-98, 107-108, 134-135, 142-145, 158, 161, and 183-191 will be pending and under examination.

Applicants maintain that the amendments to claims 183-184 and new claims 185-191 raise no issue of new matter.

Support for claim 183 may be found *inter alia* in the specification, as originally-filed, at page 18, lines 25 to 29; page 56, lines 15-23; page 61, lines 29-32; page 64, lines 13-19; and page 81, line 7 through page 82, line 13. Support for claim 184 may be found *inter alia* in the specification, as originally-filed, at page 19, lines 6 to 11; page 56, lines 23-32; page 61, line 34 through page 62, line 3; page 64, lines 13-19; and page 81, line 7 through page 82, line 13. Support for new claim 185 may be found *inter alia* in the specification, as originally-filed, at page 47, lines 10-27; page 64, lines 13-19; and page 81, line 7 through page 82, line 13. Support for new claim 186 may be found *inter alia* in the specification, as originally-filed, at page 48, line 28 through page 49, line 25; page 64, lines 13-19; and page 81, line 7 through page 82, line 13.

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Support for new claim 187 may be found inter alia in the specification, as originally-filed, at page 50, line 24 through page 52, line 18; page 64, lines 13-19; and page 81, line 7 through page 82, line 13.

Support for new claim 188 may be found inter alia in the specification, as originally-filed, at page 57, line 23 through page 58, line 1; page 61, lines 29-32; page 64, lines 13-19; and page 81, line 7 through page 82, line 13. Support for new claim 189 may be found inter alia in the specification, as originally-filed, at page 58, lines 6-34; page 61, line 34 through page 62, line 3; page 64, lines 13-19; and page 81, line 7 through page 82, line 13.

Support for new claim 190 may be found inter alia in the specification, as originally-filed, at page 60, lines 13-30; page 61, lines 29-32; page 64, lines 13-19; and page 81, line 7 through page 82, line 13. Support for new claim 191 may be found inter alia in the specification, as originally-filed, at page 60, line 32 through page 61, line 15; page 61, line 34 through page 62, line 3; page 64, lines 13-19; and page 81, line 7 through page 82, line 13.

Accordingly, applicants respectfully request that the amendment be entered.

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Sequence Rules

On page 2 of the May 5, 2003 Office Action, the Examiner alleged that this application fails to comply with the requirements of 37 C.F.R. §1.821-1.825 for the reasons set forth in the Notice to Comply with Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures and CRF Problem Report. Applicants attach hereto a copy of the Notice as **Exhibit B**. The report alleged that the CRF was unreadable. In response, applicants submit herewith as **Exhibit C** a copy of the sequence listing on paper in compliance with 37 C.F.R. §1.821-1.825, a Statement in Accordance with 37 C.F.R. §1.821(f) as **Exhibit D**, and a copy of the C.R.F. Sequence Listing as **Exhibit E**.

Restriction Requirement Under 35 U.S.C. §121

On page 2 of the May 5, 2003 Office Action, the Examiner to whom the subject application is assigned required restriction under 35 U.S.C. §121 to one of the following inventions:

I. Claims 76-77, 97-98, 107-108, 134-135, 142-145, 158, 161, drawn to a method for identifying a chemical compound which binds to a mammalian NPFF receptor, classified in class 435, subclass 7.2;

II. Claims 178-180, 183-184, drawn to a process for

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preparing a pharmaceutical composition, as it reads on, for example, an antibody (see page 44, lines 27-31 of the Specification), classified in class 435, subclass 69.6.

The Examiner alleged that inventions I-II are independent and distinct, each from the other, because the structure of the compound produced by the process of Group II is independent of the means of identifying it, especially as the functional assay of Group I would reasonably be expected to identify numerous compounds having different structures and functions.

In response to this restriction requirement, Applicants' hereby elect, with traverse, to prosecute the invention of Examiner's Group II, i.e., amended claims 183-184 and new claims 185-191 which correspond to previous claims 178-180, drawn to a process for preparing a pharmaceutical composition by performing the method steps set forth. Applicants respectfully point out that previous claims 183-184 and 178-180, and amended claims 183-184 and new claims 185-191, do not read on an antibody.

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction of Examiner's Group I from Examiner's Group II, be withdrawn in view of the fact that

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the claims of Examiner's Group I are not independent of Examiner's Groups II. Applicants maintain that the claims of Examiner's Group I and Examiner's Groups II do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group I, drawn to a method for identifying a chemical compound which binds to a mammalian NPFF receptor, are related to the claims of Examiner's Group II in that the claims in both groups use methods related to identifying chemical compounds that bind to, bind to and activate, and bind to and inhibit activation of the NPFF receptor. Thus, the claims of Groups I and II are connected in design and effect.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, Applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction,

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namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group I (drawn to a process for identifying a chemical compound) will reveal whether any prior art exists as to Group II (drawn to a process for preparing a pharmaceutical composition). Since there is no burden on the Examiner to examine Groups I-II in the subject application, the Examiner should examine all of the claims pending in this application on the merits.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 76-77, 97-98, 107-108, 134-135, 142-145, 158, 161, and 183-191 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided.

No fee, other than the fee of \$836.00 (\$726.00 for additional filing fee and \$110.00 for a one-month extension of time) is

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deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450.


Gary J. Gershik
Reg. No. 39,992

Date

John P. White
Registration No. 28,678
Gary J. Gershik
Registration No. 39,992
Attorney for Applicants
Cooper & Dunham LLP
1185 Ave of the Americas
New York, New York 10036
(212) 278-0400

Marked-up Version of the Amendments

Additions to the text are indicated by underlining; deletions are indicated by strikeout.

--183. (Amended) A process for method of preparing a pharmaceutical composition which comprises:

- a) determining whether a compound is a mammalian NPFF receptor agonist ~~using the method of claim 134, recovering the compound free of any mammalian NPFF receptor, and admixing the compound with a pharmaceutically acceptable carrier. by a method which comprises contacting cells transfected with and expressing DNA encoding the mammalian NPFF receptor with the compound under conditions permitting the activation of the mammalian NPFF receptor, and detecting an increase in mammalian NPFF receptor activity, so as to thereby determine whether the compound is a mammalian NPFF receptor agonist.~~
- (b) recovering said the compound free of any mammalian NPFF receptor; and
- (c) admixing a pharmaceutically acceptable amount of said the compound with a pharmaceutically acceptable carrier, thereby preparing the pharmaceutical composition.--

--184. (Amended) A process for method of preparing a pharmaceutical composition which comprises:

- a) determining whether a compound is a mammalian NPFF receptor antagonist ~~using the method of claim 135, recovering the compound free of any mammalian NPFF receptor, and admixing the compound with a pharmaceutically acceptable carrier by a method which comprises contacting cells transfected with and expressing DNA encoding the mammalian NPFF receptor with the compound in the presence of a known mammalian NPFF receptor agonist, under conditions permitting the activation of the mammalian NPFF receptor, and detecting a decrease in mammalian NPFF receptor activity, so as to thereby determine whether the compound is a mammalian NPFF receptor agonist;~~
- (b) recovering said the compound free of any mammalian NPFF receptor; and
- (c) admixing a pharmaceutically acceptable amount said the compound with a pharmaceutically acceptable carrier, thereby preparing the pharmaceutical composition.--